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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,727	07/08/2002	Hubert Rein	228.1010	8812

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EXAMINER	
ROGERS, JAMES WILLIAM	
ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
10/19/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/980,727	REIN ET AL.	
	Examiner	Art Unit	
	JAMES W. ROGERS	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5,6,10,16-18 and 20-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,6,10,16-18 and 20-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 07/14/2009 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10,16-18,23-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakamichi *et al.* (EP 0,580,860 A1, cited by applicants), for the reasons set forth in the office action filed 01/14/2009.

Applicants assert that the solid dispersions of Nakamichi from the figures either releases all of the active at once or essentially none of the active, thus applicants surmise none of the dosage forms are controlled release as required by the claims.

The relevance of these assertions is unclear. Firstly the figures described by applicants are only reprehensive of a few of the examples within Nakamichi, which were given solely for the purpose of illustration and were not to be construed as being limiting to their invention since many variations are possible without departing from the spirit and scope of the invention. Secondly test example 7 has a nearly linear release profile over time and is not an immediate or delayed release formulation. Furthermore those

figures referred to by applicants are only showing the release profile in two types of buffered solutions JP 1 and JP 2, with a pH of 1.2 and 6.8 respectfully and not necessarily representative of the release profile that would be observed in a subject's body. Lastly since Nakamichi encompasses the same types of compounds as presently claimed from the teachings of its entire disclosure it is inherent that the same composition will have the same properties including its release profile.

Claims 10,16-17,23-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Lentz *et al*. (WO 92/15285), for the reasons set forth in the office action filed 05/11/2007.

Applicants as previously argued in past responses state that the examiner is improperly combining one teaching of Lentz with regard to co-extruding previously processed starch with an active agent. Thus applicants surmise that the starch of Lentz is different then their own claimed starch because it is soft and rubbery and therefore above the glass transition temperature.

Firstly the examiner notes that for the claims rejected above applicants do not claim a method of making a sustained release matrix but rather the claims are drawn to a controlled release matrix. The steps of producing the matrix within the rejected claims above are attempts to limit the claims by product by process. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior

product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Since the matrix of Lentz is within the scope of applicants claimed invention the matrix of Lentz anticipates applicant's invention. Furthermore In regards to applicants assertion that the only co-extrusion process within the examples is soft and rubbery, these arguments are not found persuasive since the examples within Lentz were given solely for the purpose of illustration and were not to be construed as being limiting to their invention since many variations are possible without departing from the spirit and scope of the invention. Clearly Lentz describes that the starch could be in several physical forms depending on the processing temperature including melts and/or thermoplastic materials which would not be physically rubbery or soft, rather upon cooling they would be glass-like. Example 18 is only one very limited embodiment of the Lentz reference, a vaginal suppository and clearly is not limiting for the entire scope of the reference which teaches numerous final products besides the narrow product described within claim 18. Lentz clearly teaches that the active ingredient may be added to the starch prior to destructurization process (the processing step of the starch). See page 13 lines 5-22.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 5-6, 10, 16-18, and 20-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakamichi *et al.* (EP 0,580,860 A1), for the reasons set forth in the office action filed 01/14/2009.

Applicants assert that Nakamichi does not provide a reasoning to optimize the parameters of the temperature of the extruder and the amount of water added to the mixture during processing and therefore it would be undue experimentation to achieve the claimed invention based upon the disclosure of Nakamichi.

The examiner respectfully disagrees. As cited previously by the examiner Nakamichi teaches that the temperature used during processing should be below the decomposition points of the ingredients within the composition such as the drug, polymer, etc. Thus there is clear disclosure within the reference on the importance of optimizing temperature during processing to avoid decomposition. Nakamichi also describes how aqueous solution lowers the transition temperatures of polymer, allowing the molding temperatures to be set lower in order to prevent thermal degradation of the polymer and drug. Thus there is also a disclosure within the reference and a reason to adjust the amounts of aqueous solution during the processing of the composition. As clearly described within Nakamichi the parameters of temperature and water added are adjusted in order to prevent thermal decomposition and adjusting these parameters would not be undue experimentation since the methods of adjusting them would be routine and ordinary to one of ordinary skill in the art. It is noted by the examiner that

applicants have not argued or shown unexpected results from the optimization of these parameters.

Claims 1, 5-6, 10, 16-18, and 20-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lentz *et al.* (WO 92/15285), for the reasons set forth in the office action filed 05/11/2007.

Applicants incorporate by reference their previous arguments and present a new argument in that they do not believe the examiners specific example in figure 10 supports his position of overlapping temperature ranges since these temperatures only produce quick release dispersions and not extended release as claimed.

In regards to the portion of applicants arguments that were previously submitted, the examiner in the interest of not burdening the record will also incorporate his reply from the previous office actions in response to those previous arguments. In response to applicant's new argument, figure 10 was only referred to by the examiner to show that contrary to applicant's assertion the processing was carried out at either a constant temperature or at least a final temperature that is below applicants claimed upper limit. Thus applicant's assertion from their previously filed remarks that the temperature range is merely referring to the range of the entire extrusion process was not found persuasive since the examples clearly demonstrate that the processing temperature for at least two examples was below applicants claimed upper limit. Furthermore the figure details tablets made from example 10 which were said to be sustained release, thus it is unclear why applicants believe this formulation is quick release.

Conclusion

No claims are allowed at this time.

Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 271-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you

have questions on access to the Private PAIR system, contact the Electronic Business

Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618